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Dated: August 18, 2004

Signature:

Shawn P. Foley
(Shawn P. Foley)

1616
IFW

Docket No.:
CELLTH 3.0-003 CONT CONT VI
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Warrell et al.

Application No.: 10/759,726

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: PROCESS FOR PRODUCING ARSENIC
TRIOXIDE FORMULATIONS AND
METHODS FOR TREATING CANCER USING
ARSENIC TRIOXIDE OR MELARSOPROL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By *Shawn P. Foley*
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account

08/24/2004 RMEBRAHT 00000035 10759726

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PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/759,726	
			Filing Date	January 16, 2004	
			First Named Inventor	Raymond P. Warrell, Jr.	
			Art Unit	1616	
			Examiner Name	A. N. Pryor	
Sheet	1	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT VI

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA**	US-132,275-B1	10-15-1872	Gettings	
	AB**	US-232,807	10-05-1886	Dennett	
	AC**	US-3,700,498	10-24-1972	Kanazawa et al.	
	AD**	US-4,497,780	02-05-1985	Barin et al.	
	AE**	US-5,759,837	06-02-1998	Kuhajda et al.	
	AF**	US-2002/0183385	12-05-2002	Ellison et al.	
	AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong	
	AH**	US-6,770,304	08-03-2004	Warrell et al.	
	AI**	US-2003/0099719	05/2003	Warrell et al.	
	AJ**	US-6,723,351	04-20-2004	Warrell et al.	
	AK**	US-6,773,792	05-11-2004	Lu	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	JP-51-88620	03-08-1976			
	BB	WO-95/01789	01-19-1995			
	BC	CN-1133725	10-23-1996			
	BD	CN-1131037	09-18-1996			
	BE	CN-1122700	05-22-1996			
	BF	CN-1081104	01-26-1994			
	BG	CN-1119113	03-27-1996			
	BH	CN-1061908	06-17-1992			
	BI	CN-1121807	05-08-1996			
	BJ	CN-1079391	12-15-1993			
	BK	WO-94/02103	02-03-1994			
	BL	FR-2 539 993	03-31-1994			
	BM	DE-43 17 331	12-01-1994			
	BN	WO-95/22336	08-24-1995			
	BO	LV-11667	06-20-1997			
	BP	WO-94/02108	02-03-1994			

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878	
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogeneous leukemia", Jour.	

Examiner Signature		Date Considered	
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				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT VI

		A.M.A. 97(1):3-5, 1931	
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CD		NEUBAUER, "Arsenical cancer: a review", Arsenic Committee of the Medical Research Council, pp. 192-251, 1947	
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CJ		Arsenic, Environmental Health Criteria, 18, Geneva: WHO, 1981	
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CQ		YAMAMOTO et al., "Tumorigenicity of Inorganic Arsenic Compounds Following Intratracheal Instillations to the Lungs of Hamsters", Int. J. Cancer 40:220-223, 1987	
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CS		LI et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma", Chinese J. Oncology, 10:61-62, 1988	
CT		SUN, HONGDE et al., "32 Cases of Acute Early Granulocytic Leukemia Treated with Ai-Ling No. 1 in Combination with Chinese Medical Practice of Pattern Identification", Zhongguo Zhongxiyi Jiehe Zazhi, Vol. 12(3), 170-171, 1992	
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CV		Arsen (III)-Sulfid As ₂ S ₃ ", Gmelin's Arsenic, 8.sup.th Edition, 17:422-433, 1952	
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CY		"Inorganic Arsenic Compounds Other Than Arsenic Health and Safety Guide", Health and Safety Guide No. 70, WHO, Geneva 1992	
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CA1		AKAO et al., "Arsenic Induces Apoptosis in B-cell Leukemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102, 1055-1060, 1998 ©Blackwell Science Ltd.	
CB1		ANDRE et al., "The PML and PML/RAR α . Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996	
CC1		Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991	

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Sheet	3	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT VI

CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia: As ₂ O ₃ induces NB ₄ Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR α /PML proteins", Blood 88(3): 1052-1061, Aug. 1996. ©American Society of Hematology 1996
CE1	CHEN et al., "Use of Arsenic Trioxide (As ₂ O ₃) in the Treatment of Acute Promyelocytic Leukemia (APL):I. As ₂ O ₃ Exerts Dose-Dependent Dual Effects on APL Cells", Blood 89(9):3345-3353, 1997 ©The American Society of Hematology 1997
CF1	CHUNG et al., "Influence for Carcinoma Cell and Lymphatic Cell of Acetyl Arsonate", Yakhak Hoeji 40(5):599-607, 1996 (Abstract Only)
CG1	DE THE "L'oxyde d'arsenic: apres l'acide retinoique, un nouveau traitement cible dela leucemie aigue promyelocytaire" Medecine/Sciences, 13:867-71, 1997
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CK1	GERMOLEC et al., "Arsenic Induces Overexpression of Growth Factors in Human Keratinocytes", Toxicology and Applied Pharmacology, 141:301-318, 1996 ©Academic Press, Inc., 1996
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CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol, Suppl. 13, p. 363-65, 1989
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CU1	SCHENK, Handbook of Preparative Inorganic Chemistry, 1:603, G. Brauer, Ed., Academic Press, New York, 2.sup.nd Edition, 1963
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CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.
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CA2	XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995

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	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
	CC2	YUAN et al., "Exploring Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):17-21, 1988	
	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
	CE2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with "713": Clinical Observations and Study of Action Mode on 117 patients", J. Harbin Medical Univ. 29(3):243, 1995	
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	CM2	VOISEN et al., "Extrapolation of Animal Toxicity to Humans: Interspecies Comparisons in Drug Development", Regulatory Toxicology and Pharmacology, 12:107-116 (1990)	
	CN2	FREIRICH et al., "Quantitative Comparison of Toxicity of Anticancer Agents in Mouse, Rat, Hamster, Dog, Monkey and Man", Cancer Chemotherapy Reports, 50:219-244 (1966)	
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	CR2	ZHANG et al., "Pathologic, Cytogenetic and Molecular Assessment of Acute Promyelocytic Leukemia Patients Treated with Arsenic Trioxide (As ₂ O ₃)", Modern Pathology; (2000); pp. 954-961	
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